

Remarks

Claims 1-28 are pending in the application. Claims 22-28 are amended herein in accord with the Examiner's suggestions presented at page 4 of the latest Office Action for which Applicants hereby express their gratitude. Upon entry of this amendment, claims 1-28 will remain pending before the Examiner.

Applicants gratefully acknowledge the Examiner's indication that the § 102(e) rejections over Lightfoot *et al.* (U.S. Patent 5,998,700); over Lightfoot *et al.*(US Patent 6,339,573); and over Good *et al* (US Patent 6,084,153); as well as the § 112, first paragraph, enablement and written description rejections, have been withdrawn in view of Applicants' last Response as indicated on pages 2-3 of the Office Action.

In response to the § 112, second paragraph rejection of claims 21-28 set forth at pages 3 and 4 of the Office Action, Applicants have amended claims 22-28 above in accordance with the Examiner's suggestions. Accordingly, the rejections of these claims have been obviated. However, Applicants respectfully traverse the rejection of claim 21 as indefinite. The Examiner is correct that the claim reads "transgenic plant cells" which, as noted, means more than one cell. Applicants believe it is therefore clear to the ordinary artisan that one and only one cell would not be covered by this claim. Reconsideration and withdrawal of this rejection is hereby requested.

Next, Applicants respectfully traverse the § 102(b) and § 103(a) rejections over Long *et al.*, set forth at pages 4-7 of the Office Action. In support of their traversal, Applicants reassert the cited reference is not enabling. It fails to provide the ordinary artisan with any expectation of success. In fact, the cited reference provides nothing but an invitation to experiment. Although Long *et al.* states that "Plant nitrogen metabolism has been altered by transformation with a highly active assimilatory bacterial glutamate dehydrogenase gene," no details whatsoever are provided. There is no teaching of how one would identify such a gene. No DNA sequence information is provided. No source plasmid is identified. No restriction enzyme cleavage information is provided. There is no teaching regarding source organism for the gene. No transformation vector is provided. No transformation methods are suggested. There is no teaching regarding the target plant species. In fact, there is no proof that any transgenic plant was obtained, nor even any transgenic plant cells. Although the authors assert that nitrogen metabolism in some type of purportedly transgenic plant was altered, they do not tell in what way it was altered. They speculate that "increasing the activity of plant

nitrogen metabolism enzymes may alter plant growth”, but maybe not. They further speculate that “increased yield and protein content . . . may result,” but maybe not. They state that their unidentified bacterial GDS gene “has been altered by PCR . . . to modify the coding region” yet they provide no guidance as to what alterations were made. They assert that the 5’ non-coding region of the unidentified GDS gene has been altered, but they don’t tell how. They assert that the 3’ non-coding region has been altered, but they don’t tell how. They state that “certain codons likely to inhibit expression . . . have been altered”, but they don’t tell how. Finally, they conclude “The effects of the various sequence substitutions [none of which are identified] on gene expression in plant cells [unidentified] compared to the unmodified gene [unidentified] will be reported.” The ordinary artisan is clearly left to speculate whether any effects were observed or not. There is no teaching that the experiments in unidentified plant cells using unidentified transformation techniques (successful?) with an unidentified transformation vector, which may or may not have contained an unidentified bacterial GDH sequence, which was purportedly modified in a number of teasingly unspecified ways, had any observable effects at all.

It is irrefutable that to be a sufficiently anticipatory prior art reference under §102, the prior art reference must be enabling. The Court of Appeals for the Federal Circuit has stated, “when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all of the disclosure related to the process is within the skill of the art.” *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001, at 1005 (Fed. Cir. 1997). Long *et al.* discloses none of their starting materials. Long *et al.* discloses none of the conditions under which their processes were performed. In view of the foregoing, it is abundantly clear that this one paragraph abstract fails to meet the requirements of an anticipatory reference and the rejection should be withdrawn.

Further, regarding obviousness, Long *et al.*, provides nothing but the suggestion to experiment to one of ordinary skill in the art. It is woefully lacking in specifics of any kind, whether experimental procedures or resulting data, which might provide the ordinary artisan with the required reasonable expectation of success. To support an obviousness rejection, one must find both the suggestion, and the reasonable expectation of success, in the prior art. *In re Dow Chemical Co.*, 5 USPQ2d 1529,1531 (Fed. Cir. 1988). The reference is not enabling and fails to provide any

expectation of success to the ordinary skilled artisan. Accordingly no *prima facie* case of obviousness has been set forth, and the rejection must be withdrawn. Reconsideration is respectfully requested.

Next, claims 1-3, 5, 8, 10, 12-14, 16, 18-22, and 26-28 stand rejected under § 103(a) as obvious over Coruzzi, *et. al.* (US Patent 6,107,547) for reasons set forth at pages 7-8 of the Office Action. Applicants respectfully traverse, noting that the '547 should be removed as a reference against Applicants' claims. In support, Applicants submit herewith a copy of their Declaration Under 37 CFR §131 filed in ancestral application Serial No. 09/070,844 (now abandoned), attached to which as Exhibits A-1 and A-2 are two grant proposals from prior to the October 1994 filing date of the '547 patent, which demonstrate that Applicants' invention predates the cited reference. Reconsideration and withdrawal of this rejection is respectfully requested.

Applicants traverse the § 103(a) rejection of claims 1-5, 8-10, and 12-28 over the '547 patent in view of Long *et al.*, set forth at page 8 of the Office Action. The primary reference '547 patent is unavailable to support this rejection. The deficiencies of the secondary reference Long *et al.* have been set forth in detail above. For these reasons, Applicants respectfully request reconsideration and withdrawal of this rejection.

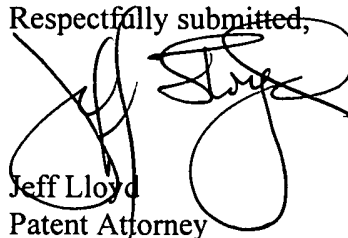
Finally, in response to the double patenting rejection set forth at page 9 of the Office Action, Applicants submit herewith a terminal disclaimer.

In view of the foregoing, Applicants believe that all claims as currently pending are in condition for allowance, and such action is respectfully requested.

The Assistant Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 and 1.17 as required by this paper to Deposit Account 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Jeff Lloyd

Patent Attorney

Registration No. 35,589

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: Saliwanchik, Lloyd & Saliwanchik

A Professional Association

P.O. Box 142950

Gainesville, FL 32614-2950

JL/fes